No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE PETITIONER

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QUESTION PRESENTED

Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

CORPORATE DISCLOSURE STATEMENT

Petitioner Helsinn Healthcare S.A. is a subsidiary of Helsinn Holding S.A. Helsinn Holding S.A. has no parent corporation, and no publicly held company holds 10% or more of its stock.

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Cases—continued:

Bayer, In re, 568 F.2d 1357 (C.C.P.A. 1978) 46
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Cases—continued:

Medicines Co. v. *Hospira, Inc.*,
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Statutes:

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Statutes—continued:

Patent Act of 1836,
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35 U.S.C. 326(a)(5) 35
35 U.S.C. 326(a)(6) 35
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Miscellaneous:

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157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011) ..... *passim*
157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) 8, 28
Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20 (2016) 48

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Miscellaneous—continued:

European Patent Convention, art. 54(2) (16th ed. June 2016) <tinyurl.com/europepriorart> 33
Examination Guidelines for Patent and Utility Model in Japan (June 2018) <tinyurl.com/japanpriorart> 33
78 Fed. Reg. 11,059 (Feb. 14, 2013) 8
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H.R. 1908, 110th Cong. (2007) 26
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H.R. Rep. No. 98, 112th Cong., 1st Sess. (2011) 7, 26, 28, 35
Korean Intellectual Property Office, *Understanding the Patent Act of the Republic of Korea* (2017) <tinyurl.com/repkoreapriorart> 33
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Merriam-Webster's Collegiate Dictionary (11th ed. 2009) 19
Patent and Trademark Office, *IP5 Statistics Report, 2016 Edition* (Nov. 2017) <tinyurl.com/ip5statistics> 31
Patent Law of the People's Republic of China, art. 22 (Dec. 27, 2008) <tinyurl.com/chinapriorart> 33
S. 3818, 109th Cong. (2006) 26
S. 1145, 110th Cong. (2007) 26
S. Rep. No. 259, 110th Cong., 2d Sess. (2008) 7, 26, 31

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 17a-52a) is reported at 855 F.3d 1356. The opinion of the district court (Pet. App. 235a-241a) is unreported. The supplemental opinion of the district court (Pet. App. 53a-231a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 1, 2017. A petition for rehearing was denied on January 16, 2018 (Pet. App. 1a-16a). The petition for a writ of certiorari was filed on February 28, 2018, and granted on June 25, 2018. This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

1. Section 3(b)(1) of the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, 285-286 (2011), provides:

> Section 102 of title 35, United States Code, is amended to read as follows:
>
> * * *
>
> (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention[.]
>
> * * *
>
> (b) EXCEPTIONS.—
>
> (1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—
>
> (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
>
> (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.
>
> * * *

2. Section 3(a) of the AIA, 125 Stat. 285, provides:

DEFINITIONS.—Section 100 of title 35, United States Code, is amended—

* * *

(2) by adding at the end the following:

* * *

(j) The term 'claimed invention' means the subject matter defined by a claim in a patent or an application for a patent.

* * *

STATEMENT

In 2011, Congress enacted the Leahy-Smith America Invents Act (AIA) to "improve the United States patent system and promote harmonization of the United States patent system" with the patent systems of other countries. Pub. L. No. 112-29, § 3(p), 125 Stat. 284, 293. The keystone of that legislation was a change in the rules governing priority—that is, who among competing inventors has the right to patent a claimed invention. Before the AIA, the first inventor had priority. In the AIA, Congress changed that rule: joining the world's other major patent systems, Congress gave priority to the first inventor to file a patent application, regardless of the date of invention.

A critical component of Congress's shift from a first-to-invent system to a first-inventor-to-file system was a new definition of prior art—the universe of existing knowledge against which an invention's patentability is measured. Before the AIA, a patent could not issue if an "invention was * * * in public use or *on sale* in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. 102(b)

(2006) (emphasis added). Congress modified that provision in various respects in the AIA, providing, as is relevant here, that an inventor is entitled to a patent unless "the claimed invention was * * * in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention." 35 U.S.C. 102(a)(1) (emphasis added).

The new catch-all provision informs the meaning of the language that precedes it, clarifying that a sale qualifies as prior art only if the sale makes the claimed invention "available to the public." The Senate committee that first introduced the catch-all provision confirmed that interpretation, as did the AIA's sponsors. And the Patent and Trademark Office (PTO) has embraced that interpretation, both in examination guidelines issued shortly after the AIA's enactment and as an amicus curiae in this case.

But in a decision "untethered to the statutory text" of the patent laws, *Limelight Networks, Inc.* v. *Akamai Technologies, Inc.*, 134 S. Ct. 2111, 2120 (2014), the Federal Circuit disagreed. Without making any meaningful effort to come to grips with the relevant statutory language, the Federal Circuit held that public disclosure of the *fact* of a commercial sale invalidates a patent, even if the claimed invention remains secret and thus is not "available to the public." That decision flouts the AIA's plain text; it is contrary to the expressed intent of the AIA's drafters; and it would frustrate the policies that the patent laws promote. Rarely does a court of appeals veer so far off course when interpreting a federal statute. The judgment of the Federal Circuit should be reversed.

A. Background

1. Nearly two centuries ago, this Court held that an inventor's "voluntary act or acquiescence in the public sale and use" of his invention before the filing of a patent

application is an "abandonment of his right." *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1, 24 (1829). The principle that a sale could bar the issuance of a patent, known as the on-sale bar, was motivated by a "reluctance to allow an inventor to remove existing knowledge from public use." *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 64 (1998). Congress first codified the on-sale bar in the Patent Act of 1836. See Pub. L. No. 24-357, § 6, 5 Stat. 117.

As enacted by the Patent Act of 1952 (and unchanged until the AIA), the statutory provision containing the on-sale bar stated that a patent could not issue if an "invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. 102(b) (2006). Construing that provision in *Pfaff*, *supra*, this Court held that two conditions must be satisfied for an invention to be "on sale": first, "the product must be the subject of a commercial offer for sale," and, second, "the invention must be ready for patenting." 525 U.S. at 67.

Of particular relevance here, both before and after this Court's decision in *Pfaff*, the Federal Circuit held that an inventor's sale of an invention to another party could constitute a qualifying "commercial offer for sale" even if it did not disclose the invention to the public. See, *e.g.*, *Special Devices, Inc.* v. *OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001); *In re Caveney*, 761 F.2d 671, 675-676 (Fed. Cir. 1985). That holding was in tension with this Court's repeated statements that the on-sale bar reached the "public sale of an unpatented article" that placed the article "in public commerce." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 148-149 (1989); see, *e.g.*, *Pfaff*, 525 U.S. at 64; *Pennock*, 27 U.S. at 23-24.

2. a. In 2011, Congress transformed the Nation's patent laws by enacting the AIA. See *Kappos* v. *Hyatt*, 566

U.S. 431, 434 n.1 (2012). The AIA's fundamental innovation was to replace the existing first-to-invent patent system with a first-inventor-to-file system. That change brought the American patent system in line with the world's other major patent systems.

As part of the shift to the first-inventor-to-file system, Congress amended the definition of prior art, which plays a foundational role in patent law. A patent is an exchange between the public and an inventor. The public gets a new and useful invention; the inventor receives exclusive rights to the invention for a limited time. Prior art is the universe of existing knowledge against which an invention's patentability is measured in order to determine whether the public has received the benefit of its bargain. If an invention is novel (*i.e.*, not "already available to the public") and nonobvious (*i.e.*, not "readily discern[able] from publicly available material"), then the invention may be patented, provided that the inventor discloses the invention in the patent and satisfies the other statutory requirements. *Bonito Boats*, 489 U.S. at 150.

In the AIA, Congress amended the statutory provision defining prior art and containing the on-sale bar. As amended by the AIA, that provision, entitled "Novelty; prior art," states that a person shall be entitled to a patent unless "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention," subject to exceptions not applicable here. 35 U.S.C. 102(a)(1).

The AIA's definition of prior art differs from its pre-AIA counterpart in three critical respects. First, and of most importance here, Congress added the catch-all phrase "or otherwise available to the public" after the phrases "in public use" and "on sale." Second, Congress eliminated the pre-AIA requirement that an invalidating

public use or sale occur "in this country." And third, Congress replaced the term "invention" with the phrase "claimed invention," which it separately defined as "the subject matter defined by a claim in a patent or an application for a patent." 35 U.S.C. 100(j).

b. The legislative history reflects that, in adding the catch-all phrase "or otherwise available to the public," Congress intended to eliminate so-called "secret sales" (*i.e.*, sales that did not make inventions available to the public) as prior art—despite the Federal Circuit decisions that had held such sales to be sufficient under the pre-AIA on-sale bar. See Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 466-475 (2012).

The phrase "or otherwise available to the public" originated in the Senate Judiciary Committee, which explained that it was adding the phrase both to "emphasize the fact that [prior art] must be publicly available" and specifically to clarify that "secret collaborative agreements, which are not available to the public, are not prior art." S. Rep. No. 259, 110th Cong., 2d Sess. 9, 39 (2008). After the Senate bill passed, the House Judiciary Committee considered a revised bill that became the AIA. The House bill contained the same catch-all phrase, and the House Judiciary Committee echoed the explanation that the phrase was intended to "emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 42-43 & n.20 (2011).

Several of the AIA's sponsors, including the two eponymous sponsors, reiterated the point in extensive floor statements. Senator Kyl explained that the new catch-all phrase operated on the preceding phrases, including "on sale," thus "limit[ing] all non-patent prior art to that which is available to the public." 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011). Senator Leahy, the lead sponsor

in the Senate, similarly explained that the statute would "do away with precedent under current law that private offers for sale or private uses or secret processes * * * may be deemed patent-defeating prior art." 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011). Representative Lamar Smith, the lead sponsor in the House, added that, "contrary to current precedent, in order to trigger the bar in the new [Section] 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." 157 Cong. Rec. H4429 (daily ed. June 22, 2011).

3. Following the AIA's enactment, the Patent and Trademark Office issued revised guidelines for examining patent applications. See 78 Fed. Reg. 11,059 (Feb. 14, 2013). Of particular relevance here, the PTO instructed its examiners that, under the AIA, a sale "must make the invention available to the public" to be prior art. *Id.* at 11,075. The PTO explained that sales "among individuals having an obligation of confidentiality to the inventor" do not qualify as prior art under the AIA. *Ibid.* The PTO later incorporated its interpretation into the Manual of Patent Examining Procedures, stating that the catch-all phrase "indicates that [Section 102(a)(1)] does not cover secret sales or offers for sale." Manual of Patent Examining Procedures § 2152.02(d) (9th ed. 2014).

B. Facts and Procedural History

1. Petitioner is a small, family-owned pharmaceutical company based in Switzerland. Petitioner focuses on the research, development, and production of innovative products that improve cancer patients' health and quality of life. This case involves petitioner's flagship drug, Aloxi®, a groundbreaking treatment for chemotherapy-induced nausea and vomiting. Aloxi is by far petitioner's most successful product, accounting for the vast majority

of petitioner's revenues worldwide. Pet. Appl. for Stay of Mandate 17 (Jan. 18, 2018).

The active ingredient in Aloxi is palonosetron. Petitioner acquired the rights to palonosetron in 1998, after another company had abandoned efforts to develop it. In 2000, petitioner submitted confidential protocols for Phase III clinical trials to the Food and Drug Administration (FDA), in which it proposed to study two novel dosages of palonosetron, 0.25 mg and 0.75 mg, which were lower than those previously studied. Petitioner, which had never before sought approval for a drug in the United States, underestimated the costs of the development and approval process. As a result, the project was in danger of being terminated. Pet. App. 114a-115a.

To keep the project going, petitioner sought a business partner. In 2001, petitioner entered into a licensing agreement (and an accompanying purchase agreement) with MGI Pharma, a small Minnesota company. J.A. 52-212, 213-250. Under the agreements, MGI agreed to make upfront payments to petitioner to fund its development efforts, and also to pay future royalties if petitioner obtained FDA approval for a palonosetron product. J.A. 69-71, 80-87. In return, MGI received the rights to purchase from petitioner any approved palonosetron product and to distribute and market the product upon approval. J.A. 60, 219. The agreements described the potential products then being tested, including the claimed invention, a 0.25 mg formulation of palonosetron. J.A. 169, 248-249. The agreements bound MGI to keep confidential petitioner's proprietary knowledge related to the products, including the proposed formulation that constitutes the claimed invention; there is no dispute that MGI honored its confidentiality obligations. J.A. 107-109, 236-238.

Crucially, while the fact of petitioner's agreements with MGI was public knowledge, petitioner's claimed invention was never disclosed to the public (either by MGI or by anyone else) before petitioner began the patent-application process. While petitioner and MGI simultaneously announced the agreements in press releases, they did not provide information about petitioner's claimed formulation to the public. J.A. 251-254. And while MGI (as a public company) filed a Form 8-K with the Securities and Exchange Commission disclosing the fact of the agreements, it redacted the proposed formulation from the supporting documents. Pet. App. 22a-24a; J.A. 255-406.

In 2002, after the successful completion of clinical trials, petitioner submitted a confidential new-drug application to FDA for a 0.25 mg dose of palonosetron; FDA ultimately approved the application. In 2003, petitioner filed a provisional patent application covering the proposed formulation. Petitioner then filed a series of further applications claiming priority to the 2003 provisional application, culminating in a 2013 application that issued as U.S. Patent No. 8,598,219. That patent expires in 2024. By virtue of its effective application date, the patent is governed by the AIA. Pet. App. 19a, 25a.[1]

2. Respondents are Teva Pharmaceutical Industries, an Israeli company that is the world's largest generic drug manufacturer, and its American affiliate. In 2011, respondents filed an application seeking FDA approval to market a generic version of petitioner's 0.25 mg palono-

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[1] This case also involved three other patents governed by the pre-AIA version of the on-sale bar. Although petitioner disagrees with the Federal Circuit's determination that the pre-AIA on-sale bar invalidated those patents, see Pet. App. 27a-34a, petitioner has not sought review of that determination.

setron product. Respondents' application included a certification that petitioner's patents were invalid or would not be infringed by respondents' generic version. Under the Hatch-Waxman Act, which establishes the framework for certain pharmaceutical patent litigation, petitioner then filed a patent-infringement action against respondents in the United States District Court for the District of New Jersey. Pet. App. 26a.

After a bench trial, the district court held that petitioner's patent was valid and would be infringed by respondents' generic version of palonosetron. Pet. App. 53a-231a, 235a-241a. As is relevant here, the court rejected respondents' argument that petitioner's agreements with MGI invalidated the '219 patent under the AIA's on-sale bar. *Id.* at 164a. The court agreed with petitioner that, under the AIA, the on-sale bar applies only if a sale (or offer for sale) makes the claimed invention available to the public. *Ibid.*

The district court determined that, while the *fact* of the agreements between MGI and petitioner was public, the description of the claimed invention was redacted from the supporting documents in MGI's Form 8-K. Pet. App. 180a. Because there was no public disclosure of the *claimed invention* as a result of the agreements, the on-sale bar did not apply and the patent was valid. *Ibid.* The district court thus enjoined respondents from manufacturing or selling their generic version of Aloxi until the expiration of petitioner's patent in 2024. *Id.* at 234a.

3. Respondents appealed to the Federal Circuit. As is relevant here, respondents argued that, under the AIA, the catch-all phrase "or otherwise available to the public" does not inform the meaning of the preceding phrase "on sale," with the result that a sale (or offer for sale) need not make the claimed invention available to the public in order to trigger the on-sale bar. See Resp. C.A. Br. 42-61; Resp.

C.A. Reply Br. 15-31. Reaffirming the PTO's guidance to patent examiners, the United States agreed with petitioner, both in an amicus brief and at oral argument, that "[t]he plain text of section 102(a)(1) makes clear that only sales or offers for sale that make an invention 'available to the public' trigger the on-sale bar, and the purpose and structure of the AIA support that plain-text reading." Gov't C.A. Br. 4 (citation omitted).

4. The Federal Circuit reversed. Pet. App. 17a-52a. In its opinion, the court did not apply the traditional tools of statutory construction, nor did it come to grips with the parties' competing interpretations of the statutory language. Instead, after reciting the statutory text, the Federal Circuit proceeded to survey a selection of the floor statements of the AIA's sponsors. *Id.* at 36a-43a.

The Federal Circuit acknowledged that the floor statements addressing the on-sale bar suggested that a claimed invention must be "available to the public" in order to defeat patentability. Pet. App. 42a. But the court observed that the only cases the AIA's sponsors "explicitly referenced" by name involved the separate "public use" bar; the sponsors did not cite the earlier Federal Circuit decisions that had held so-called "secret sales" to be sufficient under the pre-AIA on-sale bar. *Id.* at 38a. Because "[t]he floor statements do not identify any *sale* cases that would be overturned by the amendments," the court reasoned, the AIA had no effect on the preexisting judicial interpretation of the on-sale bar. *Ibid.*

The Federal Circuit went on to explain that, "[e]ven if the floor statements were intended to overrule [the pre-AIA] secret or confidential sale cases," "that would have no effect here since those cases were concerned entirely with whether the *existence* of a sale or offer was public." Pet. App. 38a (emphasis added). The court stated that "[h]ere[] the existence of the sale—*i.e.*, the [agreement]

between [petitioner] and MGI—was publicly announced in MGI's 8-K filing to the SEC." *Ibid.* The court noted that "[t]here are no floor statements suggesting that the sale or offer documents must themselves publicly disclose the details of the claimed invention before the critical date." *Id.* at 43a. The court reiterated that, "[i]f Congress intended to work such a sweeping change to our on-sale bar jurisprudence," it would have done so "by clear language." *Ibid.* (citation omitted).

Based on that reasoning, the Federal Circuit held that, "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale"—even where, as here, the counterparty was required to keep those details confidential (and the claimed invention, the specific "dosage level[]" of palonosetron, was concededly not disclosed to the public). Pet. App. 39a, 43a. Applying that holding, the court concluded that the sale to MGI triggered the AIA's on-sale bar. *Id.* at 43a, 52a.[2]

5. The Federal Circuit denied rehearing en banc. Pet. App. 2a.

Judge O'Malley, a member of the original panel, concurred in the denial of rehearing. Pet. App. 3a-16a. In the wake of the panel's failure to analyze the AIA's text in reaching its holding, Judge O'Malley proceeded to supply her own textual analysis. She reasoned that Congress did not intend to alter the meaning of the phrase "on sale" in the AIA because it retained that phrase without modification. *Id.* at 9a-10a. Seemingly for that reason, she concluded that "the AIA did not change longstanding precedent governing the on-sale bar." *Id.* at 3a-4a.

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[2] The Federal Circuit also determined that petitioner's invention was ready for patenting as of the relevant date. Pet. App. 43a-52a. Petitioner did not seek review of that determination.

Most significantly for present purposes, Judge O'Malley asserted that the new catch-all phrase "or otherwise available to the public" did not inform the meaning of "on sale." Pet. App. 8a-9a. A contrary interpretation, she reasoned, would "create redundancies" in Section 102(a)(1) and "equate 'on sale' with 'public use.'" *Id.* at 8a n.2, 10a. Judge O'Malley suggested that, in the phrase "otherwise available to the public," "'to the public' limits only 'otherwise available,'" not the preceding phrases "on sale" or "in public use." *Id.* at 9a. And she suggested that Section 102(b)(1)(B), which distinguishes between "disclosures" and "public[] disclos[ures]," supported her view that a sale need not make the claimed invention "available to the public." *Id.* at 10a-11a.

SUMMARY OF ARGUMENT

Under the plain text of the AIA, the sale of a claimed invention qualifies as prior art only if it makes the invention available to the public. The Federal Circuit made no effort to root its contrary interpretation in the statutory text. That interpretation was profoundly erroneous, and it requires reversal.

A. The plain text of the relevant provision, Section 102(a)(1), requires that a sale make the claimed invention available to the public. That provision enumerates two categories of patent-defeating prior art (claimed inventions that are "patented" and those that are "described in a printed publication") followed by a third category. The third category, in turn, sets out three additional ways of putting an invention into the public domain, with two enumerated subcategories (claimed inventions that are "in public use" and those that are "on sale") followed by a residual or catch-all subcategory (claimed inventions that are "otherwise available to the public").

Where a catch-all provision ("or otherwise available to the public") follows a list of more specific provisions, the items enumerated in the specific provisions must be read in light of the catch-all provision. That canon of statutory interpretation, which this Court has described as a "familiar" one, applies with particular force where, as here, Congress uses a term such as "otherwise" to link the catch-all provision to the preceding ones. Such a term reinforces the conclusion that the ensuing language in the catch-all provision sheds light on the meaning of the preceding provisions. The correct interpretation of the relevant language in Section 102(a)(1) is thus straightforward: a sale qualifies as patent-defeating prior art only if it makes the claimed invention "available to the public."

The broader structure of Section 102(a)(1) supports that interpretation. Under the *noscitur a sociis* canon, words in a statute are known by the company they keep. Here, the relevant characteristic—that the claimed invention be available to the public—is not only expressly identified in the catch-all subcategory, but also intrinsically shared by the two preceding enumerated categories ("patented" and "described in a printed publication"), and arguably also expressly shared by a preceding subcategory ("in public use"). Even apart from the catch-all provision, therefore, it would be natural to interpret the sole remaining subcategory ("on sale") to reach only sales that make the claimed inventions publicly available. This Court's decisions interpreting similar statutes strongly support the foregoing interpretation, and the Federal Circuit's contrary interpretation is textually unsustainable.

B. The legislative history supports the plain-text interpretation of the AIA. As early as 2005, patent-reform bills in the House and Senate proposed language requiring that prior art be available to the public. The Senate Judiciary Committee added the "otherwise available to

the public" language to the definition of prior art in 2007 for the specific purpose of making clear that so-called "secret sales" do not qualify as prior art. Congress retained similar language throughout the rest of the drafting process, and it included it verbatim in the final bill, which was enacted in 2011. And the AIA's named sponsors and other legislators repeatedly made clear that their understanding was the same as the Senate Judiciary Committee's: the additional language was intended to prevent secret sales or uses from qualifying as prior art going forward. The Federal Circuit's approach—discounting the foregoing history on the ground that Congress did not cite by name the earlier Federal Circuit decisions broadly construing the pre-AIA on-sale bar—is simply confounding.

C. The plain-text interpretation of the AIA is also consistent with the AIA's broader structure. In the AIA, Congress switched from a first-to-invent regime to a first-inventor-to-file regime for the stated purpose of harmonizing American patent law with the patent law of other countries. That change fundamentally altered the justification for the on-sale bar. Before the AIA, when patentability hinged on who was first to invent, an inventor could effectively extend the available patent term by selling the invention in secret. Under the AIA, however, an inventor who does not immediately file for a patent takes the risk that another inventor will file the first patent application and thus have priority. As a result, it is unnecessary for the on-sale bar to provide inventors with an additional incentive to enter the patent system promptly. All of the world's other major patent systems have first-to-file regimes that require a claimed invention to be available to the public in order to qualify as prior art. The Federal Circuit's interpretation would make American law an outlier, flouting Congress's statutory objective. It would also create serious incongruities with the rest of the AIA.

D. The Federal Circuit did not respond to petitioner's interpretation because it did not engage with the text of the AIA at all. Judge O'Malley, who was a member of the original panel, did advance a number of contrary textual arguments in her concurring opinion at the rehearing stage, largely tracking arguments respondents had made (and have continued to make before this Court). But none of those arguments can justify the Federal Circuit's interpretation. Those arguments either ignore the impact of Congress's changes to the on-sale bar in the AIA—including the crucial addition of the catch-all provision—or rest on mischaracterizations of petitioner's argument. Contrary to respondents' contention, Congress did not ratify the Federal Circuit's interpretation of the pre-AIA on-sale bar, and the plain-text interpretation does not create any problematic superfluity in the definition of prior art.

E. Finally, the plain-text interpretation promotes the policies underlying the patent system. The overarching goal of the patent system is to ensure that the public receives an appropriate benefit in exchange for the grant of a patent monopoly. Requiring that a sale make an invention available to the public in order to qualify as prior art is consistent with that goal. The Federal Circuit's interpretation sows substantial uncertainty, subjecting patentees to searching inquiries about their contacts and communications worldwide. And it has the perverse consequence of chilling innovation by small inventors such as petitioner, which often rely on partnerships to defray the costs and risks of developing new products. The Federal Circuit's interpretation of the AIA's on-sale bar is not just inconsistent with the statutory text and legislative history; it is also bad policy. It cannot be allowed to stand. This Court should reject the Federal Circuit's interpretation and reverse the judgment below.

ARGUMENT

UNDER THE AIA, A SALE QUALIFIES AS PRIOR ART ONLY IF IT MAKES THE CLAIMED INVENTION AVAILABLE TO THE PUBLIC

A. The Plain Text Of 35 U.S.C. 102(a)(1) Requires That A Sale Make The Claimed Invention Available To The Public

In the decision under review, the Federal Circuit ignored this Court's repeated admonition that the statutory-interpretation inquiry should begin with the text. See, *e.g.*, *Henson* v. *Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1721 (2017). And in this case, because the text answers the question presented, "that is also where the inquiry should end." *Puerto Rico* v. *Franklin California Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (internal quotation marks and citation omitted).

1. Section 102(a)(1) provides that an inventor is entitled to a patent unless "the claimed invention was patented, described in a printed publication, or in public use, on sale, or *otherwise available to the public* before the effective filing date of the claimed invention." 35 U.S.C. 102(a)(1) (emphasis added). The statute thus enumerates two categories of patent-defeating prior art—claimed inventions that are "patented" and those that are "described in a printed publication"—followed by a third category. That third category, in turn, sets out three additional ways of putting an invention into the public domain, with two enumerated subcategories (claimed inventions that are "in public use" and those that are "on sale") followed by a residual or catch-all subcategory (claimed inventions that are "otherwise available to the public").

Such catch-all provisions are a familiar feature of federal statutes. They allow Congress to "avoid the necessity of listing each matter * * * falling within" them, *CSX*

Transportation, Inc. v. *Alabama Department of Revenue*, 562 U.S. 277, 292 (2011), while still reaching "other devices not specifically enumerated but similar in purpose and effect" to the enumerated categories, *Federal Maritime Board* v. *Isbrandtsen Co.*, 356 U.S. 481, 492 (1958). And where, as here, a catch-all provision follows a list of more specific provisions, the items enumerated in the specific provisions "must be read in light of the final, comprehensive category." *Federal Maritime Commission* v. *Seatrain Lines, Inc.*, 411 U.S. 726, 734 (1973); see *Paroline* v. *United States*, 572 U.S. 434, 447 (2014).

That is especially true where Congress uses a term such as "otherwise" to link the catch-all provision to the preceding ones, as it did in Section 102(a)(1). This Court has long recognized the function that "otherwise" and analogous linking terms serve in lists of parallel words or phrases. See *United States* v. *Standard Brewery*, 251 U.S. 210, 218 (1920); *United States* v. *United Verde Copper Co.*, 196 U.S. 207, 213 (1905). Such terms, the Court has explained, confirm that the ensuing language will "relat[e] to and defin[e] the immediately preceding" language. *Standard Brewery*, 251 U.S. at 218. That makes good sense. "[O]therwise," after all, is an adverb that means "in a different way or manner." *Merriam-Webster's Collegiate Dictionary* 879 (11th ed. 2009). The use of "otherwise" thus signals that the language it accompanies necessarily connects to, and informs the meaning of, the language that precedes it.

Here, the correct interpretation of the relevant language in Section 102(a)(1) is straightforward. The catch-all subcategory "or otherwise available to the public" sheds light on the meaning of the preceding subcategories by identifying a key characteristic that those subcategories should be understood to share. When "read in light of the final, comprehensive category," therefore, "on sale"

naturally refers to a sale (or offer for sale) that makes the claimed invention publicly available. *Seatrain Lines*, 411 U.S. at 734.

The broader structure of Section 102(a)(1) supports that interpretation. Under the venerable *noscitur a sociis* canon of statutory interpretation, words in a statute are "known by the company [they] keep[]." See, *e.g.*, *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 575 (1995) (interpreting "communication[s]" to refer only to public communications because the term appeared in a list referring to "documents of wide dissemination"). That familiar interpretive principle prevents courts from "ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Ibid.* (internal quotation marks and citation omitted).

The *noscitur a sociis* canon confirms petitioner's interpretation of Section 102(a)(1). The relevant characteristic—that the claimed invention be "available to the public"—is not only expressly identified in the catch-all subcategory, but also intrinsically shared by the two preceding enumerated categories: *i.e.*, claimed inventions that are "patented" or "described in a printed publication." It is arguably also expressly shared by a preceding enumerated subcategory: *i.e.*, claimed inventions that are "in public use." See Pet. App. 9a n.2 (O'Malley, J., concurring in the denial of rehearing) (stating that "public use," like "patented" and "printed publication," "recites a disclosure that is necessarily public"); Br. in Opp. 3, 21-23 (same); but see p. 43, *infra* (discussing Federal Circuit cases construing the pre-AIA "public use" subcategory more broadly). Even apart from the catch-all provision, therefore, it would be natural to interpret the sole remaining subcategory—claimed inventions that are "on sale"—to reach only sales that make the claimed inventions avail-

able to the public. See, *e.g.*, *Gustafson*, 513 U.S. at 575; *Seatrain Lines*, 411 U.S. at 736. Put simply, Section 102 (a)(1) seeks to capture all of the ways in which an inventor can put an invention into the public domain.

2. This Court's decisions in *Seatrain Lines* and *Paroline*, *supra*, strongly support the foregoing interpretation. *Seatrain Lines* involved Section 15 of the Shipping Act of 1916, which required covered parties to report certain agreements to the Federal Maritime Commission and gave the Commission the authority to approve or reject the agreements. See 411 U.S. at 726-727. In *Seatrain Lines*, one maritime carrier contracted to acquire the assets of another. See *id.* at 729. The parties reported their agreement to the Commission under the Shipping Act, and the Commission approved the agreement. See *id.* at 730. The effect of that approval was to remove the contract from scrutiny under the federal antitrust laws. See *id.* at 728. Seatrain Lines, a competitor of the now-combined carrier, objected. See *id.* at 729-731.

The relevant statutory provision enumerated six categories of agreements the Commission could approve; it then included a catch-all category for agreements "in any manner providing for an exclusive, preferential, or cooperative working arrangement." 411 U.S. at 732. There was no question that the catch-all category, along with five of the six enumerated categories, was "expressly limited to ongoing arrangements in which both parties undertake continuing responsibilities." *Id.* at 733-734. The remaining enumerated category required parties to report agreements "controlling, regulating, preventing, or destroying competition." *Id.* at 732. Seatrain Lines argued that the Commission lacked the authority to approve the agreement because the Commission's jurisdiction extended only to agreements that created ongoing obligations and not to one-time agreements. See *id.* at 732-733.

In response, the Commission argued that the reference to "destroying competition" in the relevant category demonstrated that the provision "was intended to cover one-time, discrete transactions." *Id.* at 733-734.

The Court agreed with Seatrain Lines and held that the Commission lacked the authority to approve the agreement. See 411 U.S. at 736, 745. As is relevant here, the Court reasoned that each enumerated category "must be read in light of the final, comprehensive category," which was "clearly meant as a catchall provision, intended * * * to summarize the type of agreements covered." *Id.* at 734 (alteration in original; internal quotation marks and citation omitted). The Court explained that it was a "familiar canon of statutory construction" that "such clauses are to be read as bringing within a statute categories similar in type to those specifically enumerated." *Ibid.* "Since the summary provision is explicitly limited to 'working arrangement(s),'" the Court concluded, "it is reasonable to conclude that Congress intended this limitation to apply to the specifically enumerated categories as well." *Ibid.* (alteration in original; footnote omitted).

This Court's recent decision in *Paroline* is of a piece. There, the Court construed a statute providing restitution for losses suffered by victims of child pornography. See 572 U.S. at 443. The relevant provision enumerated five categories of covered losses—"medical services," "physical and occupational therapy," "transportation, temporary housing, and child care," "lost income," and "attorney's fees and costs"—followed by a "final catchall category for 'any other losses suffered by the victim as a proximate result of the offense.'" *Id.* at 446 (quoting 18 U.S.C. 2259(b)(3)(F)). The question presented was whether a victim had to make a showing that the claimed loss was a "proximate result of the offense" before recovering under

the five enumerated categories, even though none of those categories included a causation requirement.

The Court answered in the affirmative. Quoting from *Seatrain Lines*, the Court reiterated that it is a "familiar canon of statutory construction" that enumerated provisions in a statute must be read in light of a catch-all provision that follows them. 572 U.S. at 447 (quoting 411 U.S. at 734). Because the statute defined a "broad, final category of 'other losses suffered * * * as a proximate result of the offense,'" the Court reasoned, "[t]hat category is most naturally understood as a summary of the type of losses covered—*i.e.*, losses suffered as a proximate result of the offense." *Ibid.* (alteration in original). The Court concluded that, even though it appeared only in the catch-all provision, "the proximate-cause requirement applies to all the losses described in [the statute]." *Id.* at 448.

The logic of *Seatrain Lines* and *Paroline* resolves this case. Like the statutes at issue in *Seatrain Lines* and *Paroline*, Section 102(a)(1) contains a list of enumerated categories, followed by a catch-all category. The catch-all provision in Section 102(a)(1) expressly requires that the claimed invention be "otherwise available to the public." In addition, as with the statute in *Seatrain Lanes*, most if not all of the enumerated categories in Section 102(a)(1) intrinsically share the characteristic that is expressly set out in the catch-all category, confirming that the enumerated category of "on sale" inventions should also share that characteristic. See also *Gustafson*, 513 U.S. at 575. In short, the catch-all category "is most naturally understood as a summary" of what constitutes patent-defeating prior art: any action that puts a claimed invention into the public domain. *Paroline*, 572 U.S. at 447.

If anything, this is an easier case than *Seatrain Lines* or *Paroline*. In *Seatrain Lines*, the catch-all provision at

issue required the reporting of an agreement "in any manner providing for an exclusive, preferential, or cooperative working arrangement." 411 U.S. at 732. The catch-all provision thus did not contain a connective term such as "other" or "otherwise," and the shared characteristic—the existence of an ongoing obligation—was implicit. *Id.* at 734. Here, by contrast, the catch-all provision is introduced by "otherwise," and the shared characteristic—the public availability of the claimed invention—is explicit. 35 U.S.C. 102(a)(1). And in *Paroline*, *none* of the enumerated categories of damages intrinsically shared the characteristic that the catch-all provision described—proximate causation of the loss. See 572 U.S. at 446. Here (as in *Seatrain Lines*), by contrast, most if not all of the other enumerated categories do so. See 35 U.S.C. 102(a)(1); *Seatrain Lines*, 411 U.S. at 733-734; see also, *e.g.*, *Gustafson*, 513 U.S. at 575.

Seatrain Lines and *Paroline*, in other words, presented complications that this case does not. In each instance, however, the Court applied the "familiar canon of statutory construction" for catch-all provisions and determined that the catch-all provision at issue established a shared characteristic for preceding parallel provisions. *Paroline*, 572 U.S. at 447 (quoting *Seatrain Lines*, 411 U.S. at 734). The same conclusion follows *a fortiori* here: in light of the catch-all provision that Congress added in the AIA, a sale qualifies as patent-defeating prior art only if it makes the claimed invention "available to the public." 35 U.S.C. 102(a)(1).[3]

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[3] Respondents have forfeited any alternative argument that, even if public availability is legally required, the sale to MGI (or the subsequent disclosure of the sale) somehow made the claimed invention "available to the public" on the facts of this case. See Gov't C.A. Br. 2-3 (noting that respondents "[did] not dispute" that issue). That was

B. The Legislative History Of The AIA Supports The Plain-Text Interpretation

Because the plain text of Section 102(a)(1) resolves the question presented, "that is * * * where the inquiry should end." *Franklin California Tax-Free Trust*, 136 S. Ct. at 1946 (internal quotation marks and citation omitted). To the extent the Court wishes to consider it, however, "the legislative history * * * confirms that Congress intended the statute to mean exactly what its plain language says." *Griffin* v. *Oceanic Contractors, Inc.*, 458 U.S. 564, 574 (1982). The legislators who enacted the AIA were perfectly clear about what they intended to do (impose a public-availability requirement) and how they intended to do it (by adding the catch-all provision). If there were any lingering doubt about the meaning of Section 102(a)(1)—and there should be none—the legislative history puts the matter beyond all reasonable dispute.

1. As early as 2005, patent reform bills in the House and Senate proposed language requiring that prior art be publicly available. See H.R. 2795, 109th Cong. (2005) (proposing that new Section 102(a)(1) prohibit the issuance of a patent when "the claimed invention was patented, described in a printed publication, *or otherwise publicly*

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a prudent strategic decision, because there is no colorable argument to the contrary. The relevant inquiry is whether the "subject matter defined by a claim in a patent or an application for a patent"—here, the drug dosage and formulation—was available to the public. 35 U.S.C. 100(j). While the *fact* of the sale to MGI was public, the "details of the formulation" "w[ere not] described publicly," as respondents conceded at oral argument before the Federal Circuit. C.A. Oral Arg. at 5:30-5:38. Nor was the claimed invention sold to the public (or otherwise placed in the public domain) until long after the effective filing date of the patent application. Should this Court agree that the Federal Circuit misinterpreted Section 102(a)(1) by not requiring public availability, therefore, it must reverse the judgment below.

known" before the relevant date (emphasis added)); S. 3818, 109th Cong. (2006) (same).

The current statutory text first appeared in 2007. At that time, parallel patent reform bills were making their way through the House and the Senate. Neither bill initially contained the "otherwise available to the public" catch-all provision; each provided only that "[a] patent for a claimed invention may not be obtained if * * * the claimed invention was patented, described in a printed publication, in public use, or on sale." H.R. 1908, 110th Cong. (2007); S. 1145, 110th Cong. (2007). Shortly thereafter, however, the Senate Judiciary Committee amended its bill to add the "otherwise available to the public" language that Section 102(a)(1) now contains, and the accompanying committee report explained why:

> This Manager's Amendment also added the phrase "otherwise available to the public" to [Section] 102 to make clear that *secret collaborative agreements, which are not available to the public, are not prior art.*

S. Rep. No. 259, 110th Cong., 2d Sess. 39 (2008) (emphasis added). The report elsewhere stated that the language was added to "emphasize the fact that [prior art] must be publicly available." *Id.* at 9.

With minor variation, the catch-all provision became a fixture of subsequent patent reform bills in both houses in the next two Congresses, culminating in the enactment of the AIA in 2011. See Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 472 (2012). When it considered the bill that ultimately became the AIA, the House Judiciary Committee echoed the explanation that the catch-all provision was intended to "emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 42-43 & n.20 (2011).

The AIA's sponsors confirmed that understanding during the bill's pendency. In a floor speech just before the Senate's vote on the bill, Senator Kyl noted that "[t]he words 'otherwise available to the public' were added to section 102(a)(1) during * * * mark up of [a predecessor] bill." 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011). Directly addressing the question presented here, he explained that "[t]he word 'otherwise' makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'" *Ibid.*

What is more, Senator Kyl specified that "sales" were among the categories of prior art whose meaning the AIA clarified:

> Moreover, the fact that the clause "or otherwise available to the public" is set off from its preceding clauses by a comma confirms that it applies to both "public use" and "on sale." * * * Thus new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is predicated.

157 Cong. Rec. S1370. In short, new Section 102(a)(1) was intended to "limit[] *all* non-patent prior art to that which is available to the public." *Ibid.* (emphasis added).

Senator Kyl recognized the concern that a so-called "secret sale" could be viewed as an effort to commercialize an invention before patenting. 157 Cong. Rec. S1371. But Senator Kyl responded that there was "no reason to fear 'commercialization' that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public." *Ibid.* That was because the AIA's new first-inventor-to-file regime would "provide[] ample

incentive for an inventor to enter the patent system promptly," and there was no need for an expansive definition of prior art to create that incentive. *Ibid.* New Section 102(a)(1) thus "eliminates the use of the definition of prior art to pursue varied goals such as encouraging prompt filing or limiting commercialization" and instead "serve[s] only one purpose": to "prevent the withdrawal by an inventor of that which was already in the possession of the public." *Ibid.* (internal quotation marks and citation omitted); see pp. 31-32, *infra*.

Senator Kyl added that there were other good reasons to narrow the definition of prior art to exclude such "secret sales." 157 Cong. Rec. S1371. As he explained, the pre-AIA definition of prior art, as construed by the Federal Circuit, created "traps for unwary inventors" and "impose[d] extreme results to no real purpose." *Ibid.* Litigating the issue of whether a secret sale constituted prior art served only to "create heavy discovery costs in every patent case, and to punish small inventors who are unaware of the pitfalls of the current definition of prior art." *Ibid.*

Other sponsors of the AIA, including the two eponymous sponsors, made similar points. The AIA's lead sponsor in the Senate, Senator Leahy, made clear that Section 102(a)(1) was intended to "do away with precedent under current law that private offers for sale or private uses of secret processes * * * may be deemed patent-defeating prior art." 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011).[4] And the AIA's lead sponsor in the House, Representative Lamar Smith, echoed Senator Leahy's understanding. 157 Cong. Rec. H4429 (daily ed. June 22, 2011).

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[4] Although Senator Leahy's remarks were published after the Senate's initial vote, they preceded the final vote and were cited in the House Judiciary Committee's report. See H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 43 n. 20 (2011).

He explained that, "contrary to current precedent, in order to trigger the bar in the new [Section] 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." *Ibid.*

2. In an apparent return to the discredited methodology of *Church of the Holy Trinity* v. *United States*, 143 U.S. 457 (1892), the Federal Circuit resorted immediately to the legislative history in its opinion. Yet it cited no legislative history affirmatively supporting its interpretation. Instead, it merely sought to minimize the significance of the foregoing legislative history, suggesting that Congress could not have intended to modify the operation of the on-sale bar because it did not cite by name the Federal Circuit's decisions construing the pre-AIA on-sale bar. See, *e.g.*, Pet. App. 38a, 42a-43a.

That contention is as astounding as it is self-aggrandizing. This Court has never imposed such a legislative-history clear-statement rule on Congress even with regard to its own decisions, never mind the decisions of the Federal Circuit. It would be one thing if Congress left the statutory language untouched. See pp. 39-40, *infra* (discussing the doctrine of congressional ratification). Here, however, Congress expressly modified the relevant statutory provision by including the catch-all provision. And the AIA's sponsors made clear that, in so doing, Congress intended to "limit[] *all* non-patent prior art to that which is available to the public." 157 Cong. Rec. S1370 (statement of Sen. Kyl) (emphasis added). In order to effect that change, the AIA's sponsors were hardly obligated to tip their hat to the Federal Circuit's decisions construing the preexisting statutory language.

Perhaps belatedly recognizing the absurdity of the position taken by the original panel, Judge O'Malley took a different tack in her concurring opinion at the rehearing

stage. She noted that Congress had considered but rejected bills that eliminated sales altogether from the definition of prior art. See Pet. App. 11a-12a. But that is of no moment, because petitioner is not arguing that the AIA eliminated the on-sale bar; the question presented here is *which* sales trigger the AIA's on-sale bar.

In that regard, the drafting history strongly supports petitioner's interpretation. It shows that, starting in 2005, Congress consistently included a public-availability requirement of one kind or another in the proposed definition of prior art. See pp. 25-26, *supra*. And to the extent Congress ultimately decided to retain "on sale" as a discrete category of prior art, that decision makes eminent sense, because it preserves the substantial body of law on other aspects of the on-sale bar while clarifying that a sale must make the claimed invention publicly available in order to qualify as prior art. See Markup of H.R. No. 1249, House Committee on the Judiciary, at 101 (Apr. 14, 2011); see also pp. 40-42, *infra*.

In short, while the Federal Circuit relied exclusively on the legislative history, that history confirms what the plain text of Section 102(a)(1) already unambiguously provides: a sale qualifies as prior art only if it makes the claimed invention available to the public. The Federal Circuit's contrary interpretation is unsustainable.

C. The Structure Of The AIA Further Supports The Plain-Text Interpretation

The foregoing interpretation of Section 102(a)(1)—under which a sale must make a claimed invention publicly available in order to qualify as prior art—is also consistent with the broader structure of the new and fundamentally different patent system Congress adopted in the AIA. The Federal Circuit's interpretation, by contrast,

would create serious incongruities with the rest of the statute.

1. a. Congress's stated objective in enacting the AIA was to "improve the United States patent system and promote harmonization of the United States patent system" with the patent systems of other countries. Pub. L. No. 112-29, § 3(p), 125 Stat. 293 (2011). Congress achieved that objective primarily by changing the rules for determining priority—that is, who among competing inventors has the right to patent a claimed invention. Before the AIA, the United States had a first-to-invent regime: the first inventor was entitled to a patent, regardless of whether the inventor was the first to file a patent application that covered the claimed invention. See 35 U.S.C. 102(a) (2006).

In the AIA, the Congress switched to a first-to-file regime, thus harmonizing American law with the laws of most other major nations (including all of the other "IP5" patent systems—Europe, China, Korea, and Japan). See 35 U.S.C. 102(a)(1).[5] Under that system, the first inventor to file a patent application is entitled to a patent, even if another inventor came up with and pursued the idea first. The purpose and effect of that change was to "encourage[] the prompt filing of patent applications" by focusing the patentability inquiry solely on the date of the earliest relevant application, rather than the date of the invention. S. Rep. No. 259, 110th Cong., 2d Sess. 7 (2008).

A critical component of the switch from a first-to-invent system to a first-inventor-to-file system was Congress's new definition of prior art. Before the AIA, when patentability hinged on who was the first inventor, patent

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[5] The "IP5" patent systems are the world's largest, handling approximately 80% of patent applications worldwide. See Patent and Trademark Office, *IP5 Statistics Report, 2016 Edition* 41, 87 (Nov. 2017) <tinyurl.com/ip5statistics>.

law recognized certain categories of "secret" prior art. Most obviously, a patent could not issue if another inventor had developed the invention earlier, even if the first inventor had not disclosed the invention to the public. See 35 U.S.C. 102(g) (2006); *OddzOn Products, Inc.* v. *Just Toys, Inc.*, 122 F.3d 1396, 1401-1404 (Fed. Cir. 1997). Congress naturally eliminated that rule, and other categories of "secret" prior art, as part of the move to a first-inventor-to-file system. See Manual of Patent Examining Procedures § 2151 (9th ed. 2014).

Before the AIA, the Federal Circuit had similarly construed the on-sale bar to reach so-called "secret sales" (*i.e.*, sales that did not disclose inventions to the public). See p. 41, *infra*. Whatever the propriety of those decisions, it makes sense that Congress would have wanted the post-AIA on-sale bar to apply only to sales that put the claimed inventions into the public domain. In a first-to-invent system, an inventor could effectively extend the available patent term by selling the invention in secret. If a competitor sought to patent the invention, the original inventor could then surface, file a patent application, and claim priority. To the extent it reached "secret sales," the pre-AIA on-sale bar gave inventors an additional incentive to enter the patent system promptly.

That incentive is no longer necessary in a first-inventor-to-file system. An inventor who does not immediately file a patent application runs the risk that a rival inventor will get to the Patent Office first; the AIA thus already gives the inventor a substantial incentive to file an application promptly. As a result, it is perfectly logical that the Congress that adopted the first-inventor-to-file system would have intended the on-sale bar to reach only sales that make claimed inventions publicly available.

b. Consistent with the foregoing rationale, all of the other "IP5" patent systems—which have long since

adopted the first-inventor-to-file method—require a claimed invention to be available to the public in order to qualify as prior art.

In Europe, for example, prior art "shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application." European Patent Convention, art. 54(2) (16th ed. June 2016) <tinyurl.com/europepriorart>. In China, prior art "mean[s] the technologies known to the public both domestically and abroad before the date of application." Patent Law of the People's Republic of China, art. 22 (Dec. 27, 2008) <tinyurl.com/chinapriorart>. In Korea, "[i]f an invention is disclosed to a person who is obligated to keep it confidential, it is not public knowledge" and thus does not qualify as prior art. Korean Intellectual Property Office, *Understanding the Patent Act of the Republic of Korea* 49 (2017) <tinyurl.com/repkoreapriorart>. And in Japan, "'[p]ublicly known prior art' means prior art which has become known to anyone as an art without an obligation of secrecy." Examination Guidelines for Patent and Utility Model in Japan, pt. III, ch. 2, § 3-3.1.3 (June 2018) <tinyurl.com/japanpriorart>.

The Federal Circuit's interpretation would thus make the United States the only major patent system to treat so-called "secret sales" as prior art. That, in turn, would flout Congress's broader objective in the AIA of "promot[ing] harmonization of the United States patent systems with the patent systems commonly used" around the world. Pub. L. No. 112-29, § 3(p), 125 Stat. 293. And it would ignore the broader changes that Congress made to the patent system, also for the purpose of promoting harmonization, when it enacted the AIA.

2. a. The Federal Circuit's interpretation would create other serious anomalies in the AIA. Consider, for example, the effect of the Federal Circuit's view on the scope of the on-sale bar. If a sale could trigger the AIA's on-sale bar without making the claimed invention available to the public, the practical effect of the AIA would have been to broaden the on-sale bar dramatically. That is because the AIA eliminated the preexisting territorial limitation on the on-sale bar: namely, that an invention must have been on sale (or in public use) "in this country" in order to qualify as prior art. 35 U.S.C. 102(b) (2006); see 35 U.S.C. 102(a)(1). Under the Federal Circuit's interpretation, the on-sale bar would apply to a sale occurring anywhere in the world, regardless of whether it discloses the claimed invention to the public.

There is no indication that Congress intended to expand the scope of the on-sale bar so radically. Quite to the contrary, Congress's decision to eliminate the territorial limitation on the on-sale bar seems to have gone hand in hand with its clarification that an invalidating sale must make the claimed invention available to the public. As Senator Kyl explained in his floor statement, "a general public availability standard is a necessary accompaniment to this bill's elimination of geographic restrictions on the definition of prior art." 157 Cong. Rec. S1371. The reason is that a public sale—even in a foreign country—"is relatively hard to falsify." *Ibid.* But if even a "secret offer for sale" in a foreign country were sufficient, it "would place U.S. inventors at grave risk of having their inventions stolen through fraud." *Ibid.*

b. The Federal Circuit's interpretation would also create significant tension with the new post-grant-review procedure that Congress adopted in the AIA. See 35 U.S.C. 321-329. Congress envisioned a "more efficient

system for challenging patents that should not have issued." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 39-40 (2011). The post-grant-review procedure, one of several administrative-review mechanisms for issued patent claims, permits patentability challenges to patents that are subject to the AIA's definition of prior art. See 35 U.S.C. 321 note (1)(A). Consistent with Congress's desire to create an efficient alternative to litigation in federal court, however, the post-grant-review procedure permits only limited discovery, which is expected to last no more than a year after institution. See 35 U.S.C. 326(a)(5), (6), (11).

The post-grant-review procedure is thus not designed to handle invalidity challenges based on sales in which the claimed invention or the entire transaction is kept secret, because proving the existence of such sales would likely require onerous discovery. As Senator Kyl explained, the post-grant-review process "would be utterly unmanageable if the validity of all patents subject to review under the new system continued to depend on discovery-intensive searches for secret offers for sale and non-disclosing uses by third parties." 157 Cong. Rec. S1371. That is plainly not what Congress intended, and it further underscores why this Court should reject the Federal Circuit's interpretation.

D. The Arguments In Support Of The Federal Circuit's Interpretation Are Invalid

Remarkably, in the decision below, the Federal Circuit did not engage with the text of Section 102(a)(1) at all. In her concurring opinion at the rehearing stage, however, Judge O'Malley belatedly advanced a series of textual arguments in support of the court's ultimate conclusion that the on-sale bar was applicable, if not its precise

holding that the mere disclosure of the fact of a sale triggers the on-sale bar. See Pet. App. 3a-16a. Judge O'Malley's opinion, in turn, largely tracked arguments respondents had presented in the court of appeals and have continued to press before this Court. See *id.* at 8a-11a; Br. in Opp. 19-27.

As we will now explain, none of those textual arguments can justify the Federal Circuit's text-free interpretation of Section 102(a)(1). Those arguments misapply this Court's statutory-interpretation jurisprudence. They manufacture illusory anomalies that the plain-text interpretation would supposedly create. And they import irrelevant pre-AIA authorities into the analysis of the AIA's on-sale bar. This Court should adopt the plain-text interpretation of Section 102(a)(1) and reject the Federal Circuit's.

1. Respondents first contend that the catch-all phrase "otherwise available to the public" merely reaches an additional category of disclosures not covered by the enumerated categories in Section 102(a)(1) and thus does not inform the meaning of those categories. See Br. in Opp. 19-20; see also Pet. App. 9a (O'Malley, J., concurring in the denial of rehearing).

Respondents' conclusion does not follow from their premise. It is of course true that a catch-all phrase such as "otherwise available to the public" can encompass items "not specifically enumerated" in a statute. *Isbrandtsen*, 356 U.S. at 492; see Br. in Opp. 20 (citing, as examples, oral and video disclosures of claimed inventions). After all, a catch-all provision certainly "catches" things that the more specific preceding provisions do not. See, *e.g.*, *CSX Transportation*, 562 U.S. at 292.

But the question presented here is not whether some type of disclosure that does *not* fall within one of the enu-

merated categories nevertheless qualifies as prior art because it makes the claimed invention "available to the public." Instead, the question presented involves the interpretation of the enumerated categories themselves—specifically, whether a disclosure that does not make a claimed invention "available to the public" can nevertheless qualify as prior art. The answer to that question is no, for the reasons stated above: a catch-all provision states a shared characteristic that informs the meaning of a preceding parallel provision, especially where the characteristic is intrinsically shared by other preceding provisions as well. See pp. 18-24, *supra*.

The essence of respondents' contention is that "otherwise available to the public" is not really a catch-all provision at all; instead, it defines an independent category, with the result that the preceding categories should be construed in isolation. But that ignores the word "otherwise," which explicitly links the catch-all provision (and its shared characteristic) to the preceding provisions. See, *e.g.*, *Paroline*, 572 U.S. at 447; *Standard Brewery*, 251 U.S. at 218; *United Verde Copper*, 196 U.S. at 213. Respondents' interpretation would leave "otherwise" with no function, violating the rule against superfluity. See, *e.g.*, *Hibbs* v. *Winn*, 542 U.S. 88, 101 (2004); *Standard Brewery*, 251 U.S. at 218. In light of Congress's use of "otherwise," there can be no serious debate that "otherwise available to the public" is a catch-all provision—and, consistent with this Court's cases construing other catch-all provisions, it sheds light on the meaning of the provisions that precede it. See *Paroline*, 572 U.S. at 447; *Seatrain Lines*, 411 U.S. at 734.

2. In a similar vein, respondents contend that, under the rule of the last antecedent, the phrase "to the public" only modifies the term "available" and thus does not inform the meaning of the other subcategories of Section

102(a)(1). See Br. in Opp. 23-25; see also Pet. App. 9a (O'Malley, J., concurring in the denial of rehearing).

Again, respondents' conclusion does not follow from their premise. The rule of the last antecedent provides that "a limiting clause or phrase * * * should ordinarily be read as modifying only the noun or phrase that it immediately follows." *Barnhart* v. *Thomas*, 540 U.S. 20, 26 (2003). The question in this case, however, is not whether "to the public," as a prepositional phrase, modifies (and only modifies) "otherwise available"; it plainly does.[6] Instead, the relevant question is whether the adjectival phrase "otherwise available to the public"—as a whole—informs the meaning of the *parallel* adjectival phrases that precede it. For the reasons stated above, the answer to that question is plainly yes.

Indeed, this Court rejected a similar (and similarly off-key) invocation of the rule of the last antecedent in *Paroline*. There, the victim contended that, in the catch-all category at issue, the phrase "suffered by the victim as a proximate result of the offense" only modified the phrase "any other losses" and thus did not inform the meaning of the preceding enumerated categories of damages. See 572 U.S. at 446. Yet the Court rejected that argument, reasoning that "[o]ther canons of statutory construction * * * work against the reading the victim suggests." *Id.* at 447. So too here: the interpretive question in this case is controlled by the "familiar canon of statutory construction" that enumerated provisions in a statute must be read in light of a catch-all provision that follows them. *Ibid.*; *Seatrain Lines*, 411 U.S. at 734.

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[6] Strictly speaking, "otherwise available" is not even an antecedent, because an antecedent presupposes the existence of a relative or other pronoun. Take the phrase "the spy who came in from the cold"; "the spy" is the antecedent, and "who" the relative pronoun.

Once again, respondents' approach effectively reads the word "otherwise" out of the statute. If respondents' invocation of the rule of the last antecedent were accepted, it would leave "otherwise" with no function, because the catch-all provision would shed no light on the meaning of the preceding provisions. This Court has previously refused to create superfluity by applying the rule of the last antecedent. See *United States* v. *Hayes*, 555 U.S. 415, 425-426 (2009). The only way to give "operative meaning" to "otherwise" is to read "otherwise available to the public" as qualifying the preceding categories. *Ibid.* In any event, in light of the structure of Section 102(a)(1) more generally and the catch-all provision specifically, the rule of the last antecedent simply does not apply here.

3. Respondents further contend that Congress ratified the Federal Circuit's interpretation of the pre-AIA on-sale bar by retaining the phrase "on sale" in Section 102(a)(1). See Br. in Opp. 20-21; see also Pet. App. 9a-10a (O'Malley, J., concurring in the denial of rehearing).

The doctrine of congressional ratification is likewise inapplicable. As a general matter, the Court presumes that Congress was "aware of an administrative or judicial interpretation of a statute," and intended to "adopt that interpretation when it re-enacts a statute." *Lorillard* v. *Pons*, 434 U.S. 575, 580 (1978). But "the doctrine of congressional ratification applies only when Congress reenacts a statute without relevant change." *Holder* v. *Martinez Gutierrez*, 566 U.S. 583, 593 (2012).

The AIA does not satisfy that requirement. Most obviously, in the AIA, Congress did not merely retain the phrase "on sale"; it added the catch-all phrase "or otherwise available to the public." 35 U.S.C. 102(a)(1). Congress also eliminated the pre-AIA requirement that an invalidating public use or sale occur "in this country," and it

replaced the term "invention" with the defined phrase "claimed invention." 35 U.S.C. 100(j). And, of course, Congress fundamentally changed the nature of the American patent system by shifting from a first-to-invent system to a first-inventor-to-file system, thus eliminating one possible rationale for the on-sale bar. See pp. 31-32, *supra*. Collectively, those changes foreclose reliance on the congressional-ratification doctrine.

Indeed, by retaining the phrase "on sale" but adding the catch-all phrase "or otherwise available to the public," Congress chose a sensible way of amending the statute to achieve its desired objective. As respondents correctly note, there was a substantial body of pre-AIA law addressing various aspects of the on-sale bar. See Br. in Opp. 20-21; see also Pet. App. 14a-16a & n.5 (O'Malley, J., concurring in the denial of rehearing). Much of that law had nothing to do with the public availability of a claimed invention.

For example, this Court established a two-prong test for determining whether an invention is "on sale," considering (1) whether the product was the subject of a commercial offer of sale and (2) whether the invention is ready for patenting. See *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998). The Federal Circuit has elaborated on that test in a series of cases on what constitutes a commercial sale, see, *e.g.*, *Medicines Co.* v. *Hospira, Inc.*, 827 F.3d 1363, 1374-1379 (Fed. Cir. 2016) (en banc), and when a claimed invention was ready for patenting, see, *e.g.*, *August Technology Corp.* v. *Camtek, Ltd.*, 655 F.3d 1278, 1288-1290 (Fed. Cir. 2011). None of those authorities bears on the question presented here: namely, whether a

claimed invention must be made available to the public in order to qualify as prior art under the AIA.[7]

Before the AIA, however, the Federal Circuit had also applied the on-sale bar even if an inventor's sale of an invention to another party did not disclose the invention to the public. For example, in *Special Devices, Inc.* v. *OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), the court held that a patentee's contract with a supplier to manufacture the product embodying an invention constituted a disqualifying "sale," even though the production activity and the invention remained secret. See *id.* at 1357. Similarly, in *In re Caveney*, 761 F.2d 671 (Fed. Cir. 1985), the court upheld the application of the on-sale bar to an offer to sell the claimed invention to a single entity, even though the counterparty "kept the claimed invention secret from the purchasing public" and the sale activity was "kept secret from the trade." *Id.* at 674-675.

The inclusion of the catch-all phrase "or otherwise available to the public" clarifies that the AIA on-sale bar should be construed differently from the pre-AIA on-sale bar in those cases; under the AIA, a sale must make a claimed invention available to the public in order to trigger the on-sale bar. See pp. 18-24, *supra*.[8] At the same

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[7] The Federal Circuit's cases on whether a commercial sale has taken place consider whether the fact of the sale has been disclosed as one factor in the analysis. See, *e.g.*, *Medicines*, 827 F.3d at 1376. In attaching significance to the disclosure of the *fact* of the sale to MGI, the Federal Circuit appears to have relied on those cases. See, *e.g.*, Pet. App. 35a-36a, 38a-39a; see also *id.* at 4a-7a (O'Malley, J., concurring in the denial of rehearing). But those cases are inapposite here, because the question before this Court is not whether a sale took place, but instead whether the sale triggered the AIA on-sale bar.

[8] This case presents no occasion for the Court to consider whether those Federal Circuit cases correctly construed the pre-AIA version of the on-sale bar. See p. 10 n.1, *supra*.

time, the retention of the phrase "on sale" avoids "throw-[ing] the baby out with the bath water," *Federal Trade Commission* v. *Actavis*, 570 U.S. 136, 157 (2013), because it preserves the substantial body of law on other aspects of the on-sale bar. Far from ratifying *every* aspect of preexisting law, Congress acted with precision in order to modify the aspect of preexisting law with which it disagreed.

4. Respondents contend that petitioner's interpretation of Section 102(a)(1) would create superfluity in various respects. See Br. in Opp. 23-27; see also Pet. App. 10a-11a (O'Malley, J., concurring in the denial of rehearing). That is incorrect.

a. Respondents first suggest that it would be redundant for the catch-all subcategory "or available to the public" to inform the meaning of the preceding categories, because one of those categories, "in public use," already reflects public activity. See Br. in Opp. 23; see also Pet. App. 9a n.2 (O'Malley, J., concurring in the denial of rehearing).

To the extent that public availability of the claimed invention is inherent in the concept of "public use," however, that does not constitute problematic redundancy; it merely means that the "in public use" subcategory, like the "patented" and "described in a printed publication" categories that precede it, already embodies the concept of public availability, with the catch-all subcategory "or otherwise available to the public" picking up other forms of public availability beyond the enumerated ones. There is nothing odd about the notion that the relevant characteristic in a catch-all provision is intrinsically shared by some of the preceding enumerated categories as well; if anything, that supports petitioner's interpretation, rather than undermining it. See pp. 20-21, *supra*; *Seatrain Lines*, 411 U.S. at 733-734.

In any event, despite the word "public" in the phrase "in public use," the Federal Circuit had construed the pre-AIA version of the public-use bar to reach some uses that did not disclose the claimed inventions to the public. For example, in *New Railhead Manufacturing, L.L.C.* v. *Vermeer Manufacturing Co.*, 298 F.3d 1290 (Fed. Cir. 2002), cert. denied, 537 U.S. 1232 (2003), the court applied the public-use bar where the inventor allowed an acquaintance to test a drill embodying the patented method, even though the method was not otherwise available to the public. See *id.* at 1298. And in *Beachcombers* v. *WildeWood Creative Products, Inc.*, 31 F.3d 1154 (Fed. Cir. 1994), the court applied the public-use bar where the designer of a patented invention displayed it at a party but did not otherwise disclose it to the public. See *id.* at 1159-1160. To the extent there was ambiguity about the scope of the public-use bar as well as the on-sale bar, the AIA eliminated that ambiguity going forward, making clear that a public use, like a sale, must make the claimed invention available to the public. Indeed, as the Federal Circuit acknowledged, the AIA's drafters did cite several pre-AIA public-use cases as examples of the "extreme results" the AIA was designed to avoid. Pet. App. 38a.

b. Respondents further suggest that requiring sales to make the claimed invention available to the public would rob the on-sale bar of any meaning independent from the public-use bar. See Br. in Opp. 21; see also Pet. App. 10a (O'Malley, J., concurring in the denial of rehearing).

That concern is unfounded. To be sure, the on-sale bar and the public-use bar may both apply to the same claimed invention: an invention that is "on sale" can also be "in public use." Indeed, when the Court first articulated the on-sale bar, it treated "sale" and "use" together. See *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1, 23-24 (1829).

But any overlap would exist under either interpretation; it depends on the respective meanings of "sale" and "use," not on whether those actions make the claimed invention available to the public.

At any rate, under petitioner's interpretation, the on-sale and public-use bars would serve independent functions. For example, "[an] offer to sell is enough to bar patentability whether or not the offer is accepted," *A.B. Chance Co.* v. *RTE Corp.*, 854 F.2d 1307, 1311 (Fed. Cir. 1988), while "public use" requires "actual use by someone at some point," *Minnesota Mining & Manufacturing Co.* v. *Chemque, Inc.*, 303 F.3d 1294, 1307 (Fed. Cir. 2002), cert. dismissed, 538 U.S. 972 (2003). As a result, the on-sale bar could apply even where a claimed invention is not yet in public use (if the product is sold but not used, or an offeree declines an offer to sell the product embodying the invention), and the public-use bar could apply even where the invention is not yet on sale (if the product enters the public domain without a sale or offer to sell, such as through an inventor's own use). The critical point is that, under petitioner's interpretation, the on-sale and public-use bars would not be coterminous. See *Dart Industries, Inc.* v. *E.I. du Pont de Nemours & Co.*, 489 F.2d 1359, 1364 & n.8 (7th Cir. 1973) (Stevens, then-J.), cert. denied, 417 U.S. 933 (1974).

c. Respondents also contend that, under petitioner's interpretation, Section 102(a)(1) would conflict with an exception in Section 102(b)(1) for certain disclosures of inventions made before a patent's effective filing date. See Br. in Opp. 25-27; see also Pet. App. 10a-11a (O'Malley, J., concurring in the denial of rehearing). According to respondents, because Congress used the term "disclosure" in Section 102(b)(1)(A) and the phrase "public[] disclos[ure]" in Section 102(b)(1)(B) to describe carve-outs from the definition of prior art in Section 102(a)(1), some

of the covered prior art must not be available to the public. A contrary interpretation, they assert, would render the word "public[]" in Section 102(b)(1)(B) redundant.

That contention misunderstands Section 102(b)(1). That provision excludes certain disclosures from the scope of prior art if they are made within one year before the patent's effective filing date. The exceptions generally apply only to disclosures made by an inventor or someone who obtained the subject matter from an inventor. Section 102(b)(1)(B), however, creates a limited additional exception for disclosures made by third parties; if an inventor "publicly disclose[s]" the "subject matter" of the invention first, then later disclosures (even by third parties) will be exempt if they are made within the one-year period.

By its terms, therefore, Section 102(b)(1)(B) contemplates an *earlier* disclosure of the "subject matter" of the invention. That is a critical distinction. Section 102(b)(1) generally refers to "a disclosure" that otherwise would qualify as prior art "under subsection (a)(1)": *i.e.*, a disclosure that makes the claimed invention available to the public. See pp. 18-24, *supra*. Section 102(b)(1)(A) explicitly excludes certain Section 102(a)(1)-qualifying disclosures. Section 102(b)(1)(B), however, refers to something different: namely, an earlier disclosure of the "subject matter" that is ultimately included in a later Section 102(a)(1)-qualifying disclosure. By including the word "publicly" in Section 102(b)(1)(B), Congress made clear that the earlier disclosure of the subject matter, like the later disclosure, must be public. So understood, the use of "public[]" in Section 102(b)(1)(B) is not redundant, and it is entirely consistent with the plain-text understanding that the triggering action in Section 102(a)(1) must make the claimed invention publicly available.

E. The Plain-Text Interpretation, Not The Federal Circuit's, Better Promotes The Policies Underlying the Patent System

Finally, petitioner's interpretation of Section 102(a)(1) better serves the policies underlying the patent system. It preserves the basic *quid pro quo* of patent law. It prevents uncertainty about the status of prior art that would be harmful to the patent system. And it encourages innovation by affording small inventors an opportunity to develop their inventions.

1. A public-availability requirement is consistent with the fundamental compromise underlying our Nation's patent system. A patent, in effect, is a trade. An inventor gives the public a useful invention and gets a monopoly in exchange. See *Brenner* v. *Manson*, 383 U.S. 519, 534 (1966). That bargain makes no sense if the public already has the invention, because "[t]here would be no quid pro quo—no price for the exclusive right or monopoly conferred upon the inventor." *Pennock*, 27 U.S. at 23. The law, therefore, requires that an invention be both novel and nonobvious. See 35 U.S.C. 102, 103. Together, those requirements prohibit an inventor from obtaining a patent on anything that is "already available to the public" or "readily discern[able] from publicly available material." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989).

The function of prior art is to define what was in the public domain before the invention. And in interpreting the definition of prior art, a court should naturally be guided by that function. In cases involving printed publications, for example, lower courts have held that "[t]he date on which the public actually gained access to the invention * * * is the focus of the inquiry." *In re Bayer*, 568 F.2d 1357, 1361 (C.C.P.A. 1978); see *In re Hall*, 781 F.2d 897, 898-899 (Fed. Cir. 1986). And in interpreting

the on-sale bar itself, this Court has cited the "reluctance to allow an inventor to remove existing knowledge from public use." *Pfaff*, 525 U.S. at 64; see *Bonito Boats*, 489 U.S. at 148-149; *Pennock*, 27 U.S. at 23-24.

Petitioner's interpretation of Section 102(a)(1) is consistent with the function of prior art more generally—and the on-sale bar specifically—in the patent system. A sale to a party obligated to keep an invention confidential, such as petitioner's sale to MGI, does not make the claimed invention available to the public, even if the public knows that a sale has taken place. Permitting petitioner to obtain a patent would therefore not violate the basic *quid pro quo* of patent law, because it would in no way "remove existent knowledge from the public domain." *Graham* v. *John Deere Co.*, 383 U.S. 1, 6 (1966).

2. If it is allowed to stand, the Federal Circuit's interpretation will unleash significant uncertainty throughout the patent system.

For patents to stimulate innovation, their owners must be able reliably to predict their strength. Indeed, "predictability as to the validity of patents" was a core rationale for the establishment of the Federal Circuit in the first place. See Nancy T. Gallini, *The Economics of Patents: Lessons from Recent U.S. Patent Reform*, 16 J. Econ. Persp. 131, 134 & n.4 (2002). The Federal Circuit's decision in this case, however, makes a mockery of that interest. As it stands, the decision will potentially expose patentees to discovery-intensive inquiries into any contacts and communications with third parties regarding the invention—not just in the United States but anywhere in the world, as a result of the AIA's territorial expansion of the definition of prior art. See 157 Cong. Rec. S1371 (statement of Sen. Kyl). That is exactly the kind of impractical burden Congress sought to protect against when

it set out to "provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries." Pub. L. No. 112-29, § 3(o), 125 Stat. 293.

3. By contrast, if it is adopted by this Court, petitioner's interpretation will foster the collaborative work that leads to innovation, especially by small inventors. A patent functions as an "incentive to inventors to risk the often enormous costs in terms of time, research, and development." *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 480-481 (1974). This is true across all industries, but it is particularly true in the pharmaceutical industry, where the discovery of new drugs is expensive and unpredictable. See generally Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20 (2016) (estimating the total pre-approval cost of developing a new drug at $2.6 billion). Even large pharmaceutical companies enter into development partnerships to share risk and defray cost. Small companies such as petitioner often have no choice: they must enter into such partnerships because they do not have the resources to develop and bring drugs to market on their own.

The Federal Circuit's interpretation puts the small companies that have to seek such partnerships at a marked disadvantage. Under the Federal Circuit's rule, any public reference to the existence of development arrangements could qualify as patent-defeating prior art. And where, as here, the development partner is itself a relatively small company, the securities laws may compel disclosure of the material fact that such an agreement exists. See Pet. App. 38a.

At a minimum, therefore, the Federal Circuit's decision has the "potential to chill deals between small bio/pharma companies and potential commercialization

partners." Andrew D. Cohen & Irena Royzman, *The Federal Circuit's First Application of the AIA's On-Sale Bar: Implications for Bio/Pharma*, Biologics Blog (May 16, 2017) <tinyurl.com/biologicsblog>. And at worst, it will prevent small companies such as petitioner from bringing new drugs to market altogether, with obvious harm to the consumers who depend on those products.

The Federal Circuit's interpretation of Section 102(a)(1) is thus not only inconsistent with the statutory text and legislative history; it is also bad policy. Rarely in a statutory-interpretation case do all of the relevant considerations point so clearly in the same direction. The Federal Circuit's decision is indefensible. Its judgment should accordingly be reversed.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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